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OCT 11 2002

510(k) Summary

General Information

Classification	Class II
Trade Name	*enCircle™* Localization Device
Submitter	Vivant Medical, Inc. 1916-A Old Middlefield Way Mountain View, CA 94043 650-694-2900
Contact	Steven Kim Director, Research & Development

Intended Use

The *enCircle™* Localization Device is intended for localization of non-palpable breast lesions.

Predicate Devices

Breast Lesion Localization Device – Vivant Medical, Inc.	K003439
Bovie Hand Control – Sybron Corporation	K790187

Device Description

The *enCircle™* Localization Device is a disposable instrument consisting of a curved localization element and a needle cannula delivery system. The device is used to localize non-palpable breast lesions to facilitate surgical excision of the lesions.

Materials

All materials used in the manufacture of the *enCircle™* Localization Device are suitable for this use and have been used in numerous previously cleared products.

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Testing

In-Vitro testing, comparing the performance of the *enCircle™* Localization Device versus the previously cleared Vivant Breast Lesion Localization Device, revealed equivalent performance with improved consistency of deployment.

Summary of Substantial Equivalence

The *enCircle™* Localization Device is equivalent to the original device from Vivant Medical as well as the RF Electrosurgical predicate product. The indications for use, basic overall function, methods of manufacturing, and materials used are substantially equivalent. Vivant Medical believes the *enCircle™* Localization Device is substantially equivalent to existing legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 11 2002

Mr. Steven Kim
Director, Research and Development
Vivant Medical, Inc.
1916-A Old Middlefield Way
Mountain View, CA 94043

Re: K022286
Trade/Device Name: enCircle™ Localization Device
Regulation Number: 878.4800
Regulation Name: Manual surgical instrument for general use
Regulatory Class: II
Product Code: KNW
Dated: July 12, 2002
Received: July 15, 2002

Dear Mr. Kim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

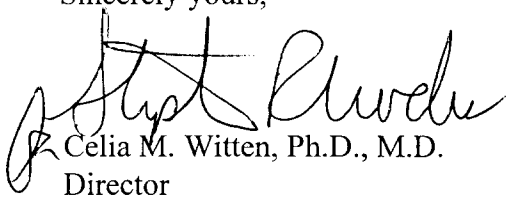
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K022286

Indications for Use

510(k) Number (if known):	This application
Device Name:	*enCircle™* Localization Device
Indications for Use:	The *enCircle™* Localization Device is intended for localization of non-palpable breast lesions.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The-Counter Use _ (Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

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